K096387

SEP 28 2009

510(k) Summary

Sponsor: SIGNUS Medizintechnik GmbH
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Contact Person: Jörg Degen, Regulatory Affairs, QM

Proposed Trade Name: KAINOS®+

Device Classification Class II

Classification Name: Bone void filler, calcium compound

Regulation: 888.3045

Device Product Code: MQV

Device Description: KAINOS®+ is a synthetic, resorbable calcium phosphate bone void filler with a trabecular structure. It is an osteoconductive material which provides a porous scaffold upon which bone formation can occur. KAINOS+ is available in granule or block-shaped forms.

Intended Use: KAINOS®+ is intended for use as a bone void filler for bony voids or gaps of the skeletal system (extremities, spine and pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. KAINOS®+ is a bone filler without initial mechanical properties. Therefore rigid fixation techniques may often be recommended. When packed into a bony site, KAINOS®+ gradually resorbs and is replaced with bone during the healing process.

Materials: KAINOS®+ is manufactured from hydroxyapatite and tricalcium phosphate according to ASTM F1088 and F1185.

Substantial Equivalence: Documentation was provided which demonstrated the KAINOS®+ to be substantially equivalent to previously cleared devices. These include: MasterGraft™ (Medtronic Sofamor Danek USA – K020986), MCBP™ (Biomatlante – K032268), PLEXUR P (Osteotech, Inc. – K080511) and Vitoss™ (Orthovita, Inc. – K0994337 and K081439). The substantial equivalence is based upon equivalence in material, basic design/size, intended use, indications, anatomic sites and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 2 8 2009

SIGNUS Medizintechnik GmbH
% Karen E. Warden, Ph.D.
Representative/Consultant
8202 Sherman Road
Chseterland, Ohio 44026

Re: K090387
Trade/Device Name: KAINOS® +
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: August 26, 2009
Received: August 26, 2009

Dear Dr. Warden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K090387

Device Name: **KAINOS®+**

Indications for Use:

KAINOS®+ is intended for use as a bone void filler for bony voids or gaps of the skeletal system (extremities, spine and pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. KAINOS®+ is a bone filler without initial mechanical properties. Therefore rigid fixation techniques may often be recommended. When packed into a bony site, KAINOS®+ gradually resorbs and is replaced with bone during the healing process.

Prescription Use __X__ OR Over-the-Counter Use_____

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FOR M. MELKERSON

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090387